

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

### 1. Why am I being given VABYSMO?

VABYSMO contains the active ingredient faricimab. VABYSMO is used to treat the following eye disorders:

- neovascular (wet) age-related macular degeneration (nAMD)
- diabetic macular oedema (DMO)
- macular oedema secondary to retinal vein occlusion.

For more information, see Section [1. Why am I being given VABYSMO?](#) in the full CMI.

### 2. What should I know before I am given VABYSMO?

You must not be given VABYSMO if you have ever had an allergic reaction to faricimab or any of the ingredients listed at the end of this CMI.

You must not be given VABYSMO if you have an infection in or around your eye, or inflammation in your eye.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I am given VABYSMO?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with VABYSMO and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How is VABYSMO given?

- VABYSMO must be injected into your eye every month initially. Thereafter, the frequency of the ongoing injections will be determined by your doctor.

More instructions can be found in Section [4. How is VABYSMO given?](#) in the full CMI.

### 5. What should I know while I am being given VABYSMO?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Tell your doctor if you experience any problems during the treatment.</li><li>• Women who could become pregnant should use effective contraception during treatment and for at least 3 months after the last injection of VABYSMO.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• You may not see as well after you are given VABYSMO and after the associated eye examinations. This is temporary. Do not drive or use machines until your eyesight has returned to normal.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• It is unlikely that you will have to store VABYSMO at home. If you have to store it, keep it in the refrigerator at 2°C to 8°C (do not freeze) in the outer carton.</li></ul>

For more information, see Section [5. What should I know while I am being given VABYSMO?](#) in the full CMI.

### 6. Are there any side effects?

Common side effects may include eye pain, watery eyes, moving spots (floaters) or shadows in your vision

Serious side effects may include gradual or sudden decrease or changes in your vision, sudden onset of eye pain, a higher number of spots in the front of the eye (floaters), increased sensitivity to light, red tint to your vision, blood or redness of your eye, small marks or scratches on the eye surface with pain or tenderness when you touch the eye, gritty feeling in the eye.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

# VABYSMO®

Active ingredient(s): *faricimab*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using VABYSMO. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using VABYSMO.**

### Where to find information in this leaflet:

1. [Why am I being given VABYSMO?](#)
2. [What should I know before I am given VABYSMO?](#)
3. [What if I am taking other medicines?](#)
4. [How is VABYSMO given?](#)
5. [What should I know while being given VABYSMO?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

## 1. Why am I being given VABYSMO?

VABYSMO contains the active ingredient *faricimab*.

Faricimab belongs to a group of medicines called antineovascularisation agents.

VABYSMO is injected into the eye by your doctor to treat adults with the following eye disorders:

- neovascular (wet) age-related macular degeneration (nAMD)
- diabetic macular oedema (DMO)
- macular oedema secondary to retinal vein occlusion (RVO).

These conditions affect the macula, the central part of the retina (the light-sensitive layer at the back of the eye) that is responsible for sharp, detailed vision.

nAMD is caused when tiny, abnormal blood vessels grow in the retina. The abnormal vessels leak blood or fluid in the macula and can form scars that cause vision to get worse and may result in permanent blind spots.

DMO is caused by leaky blood vessels that cause swelling of the macula.

RVO is a blockage of the blood vessels (veins) in the retina. Due to the increased pressure within these blood vessels, there is leakage of fluid into the retina, causing swelling of the macula (macular oedema).

### How VABYSMO works

VABYSMO specifically recognises and blocks the activity of proteins known as angiopoietin-2 and vascular endothelial growth factor A. When these proteins are present in higher levels than normal, they can cause the growth of abnormal blood vessels and damage to the normal vessels, with leakage into the retina. This causes swelling of the retina or damage to the layers of the retina, which can

negatively affect vision. By attaching to these proteins, VABYSMO can block their actions and may improve disease and/or slow down worsening of the disease, thereby maintaining your vision.

If you have any questions about VABYSMO, how it works or why this medicine has been prescribed for you, ask your doctor.

## 2. What should I know before I am given VABYSMO?

### Warnings

#### Do not use VABYSMO if:

- you are allergic to faricimab, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

Some symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

- If you have or suspect you have an infection in or around your eye.
- If you have inflammation in or around your eye (may be indicated by pain and/or redness)

#### Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition
- have glaucoma (an eye condition usually caused by high pressure in the eye)
- have a history of seeing flashes of light or floaters (dark floating spots) or if you have a sudden increase in the size and number of floaters
- have had eye surgery in the last four weeks or if eye surgery is planned in the next four weeks.
- have ever had any eye diseases or eye treatments
- have had a stroke or experienced any signs of a stroke, such as weakness or paralysis of limbs or face, difficulty speaking

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

- VABYSMO should not be used during pregnancy unless the potential benefit outweighs the potential risk to your unborn child.

Check with your doctor if you are pregnant or intend to become pregnant.

Should you become pregnant during treatment with VABYSMO, tell your doctor.

Women who are able to become pregnant should use effective contraception during treatment and for at least 3 months after your last injection of VABYSMO.

- Talk to your doctor if you are breastfeeding or intend to breastfeed. VABYSMO is not recommended during breastfeeding because it is not known whether VABYSMO passes into human milk.

### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect VABYSMO.**

### 4. How is VABYSMO given?

**How much VABYSMO is given**

- The recommended dose is 6 mg (0.05 mL) of VABYSMO, injected into your eye.
- The frequency of injections will be determined by your doctor based on the condition of your eye.

**nAMD and DMO:**

- You will be treated with one injection every month for the first 4 months.
- Thereafter, you may receive injections into your eye up to every 4 months.

**RVO:**

- You will be treated with one injection every month for a minimum of 3 months.

**Thereafter, you may receive injections less frequently.**

**How you will be given VABYSMO**

- VABYSMO is injected into your eye (intravitreal injections) by a doctor experienced in giving eye injections.

**How long will you be given VABYSMO**

- VABYSMO is intended as a long-term treatment. Your doctor will regularly monitor your condition to check that the treatment is having the desired effect.

**If you miss a dose of VABYSMO**

If you miss a dose, schedule a new appointment with your doctor as soon as possible. **Do not wait until the next planned dose.**

**Before stopping treatment with VABYSMO**

- If you are considering stopping treatment with VABYSMO, discuss this with your doctor.

Stopping treatment may increase your risk of vision loss and your vision may worsen.

- Discuss suitable alternatives with your doctor, to determine the best treatment for you.

**If you are given too much VABYSMO**

Your doctor will ensure you are given the correct amount of VABYSMO. If you think that you have been given too much VABYSMO, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

### 5. What should I know while being given VABYSMO?

**Things you should do**

- If you experience any problems during the treatment, tell your doctor.

**Call your doctor straight away or go to the emergency department if you:**

- develop sudden vision loss or change in vision
- develop signs of a possible eye infection or inflammation, such as worsening redness of the eye or blood in and around the eye, eye pain, increased eye discomfort, blurred or decreased vision, an increased number of floaters (small particles) in your vision, increased sensitivity to light

Remind any doctor or dentist you visit that you are using VABYSMO.

**Things you should not do:**

- Do not stop treatment with VABYSMO unless your doctor tells you to.  
Stopping treatment may increase your risk of vision loss and your vision may worsen.

**It is important for you to know that:**

- there is no information about injecting VABYSMO into both eyes at the same time. Use in this way may lead to an increased risk of experiencing side effects.
- injections with VABYSMO may cause a temporary increase in eye pressure (intraocular pressure) in some patients within 60 minutes of the injection. Your doctor will monitor this after each injection.
- your doctor will check whether you have other risk factors that may increase the chance of a tear or detachment of one of the layers at the back of the

eye, in which case VABYSMO must be given with caution.

- There is a risk of blood clots blocking blood vessels, which may lead to a heart attack or stroke with intravitreal injections of VABYSMO. However, this is a theoretical risk. **Go to your nearest emergency room immediately if you experience signs of a stroke, such as weakness or paralysis of limbs or face or difficulty speaking.**

### Monitoring and care during your treatment with VABYSMO

Your doctor will monitor your condition throughout your treatment with VABYSMO to allow for prompt medical assistance if necessary. Follow your doctor's instructions for how to care for the treated eye. These instructions include but are not limited to the following:

#### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how VABYSMO affects you.**

You may not see as well after VABYSMO is injected into your eye and after the eye examinations associated with VABYSMO. Do not drive or use machines until your eyesight has returned to normal.

#### Looking after your medicine

It is unlikely that you will have to store VABYSMO at home. If you have to store it:

- Store VABYSMO in the refrigerator at 2°C to 8°C in the original carton to protect from light.
- Prior to use, the unopened vial or pre-filled syringe may be kept at 20°C to 25°C for up to 24 hours.
- Do not freeze. Do not shake.
- Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

#### Less serious side effects

Less serious side effects	What to do
<b>Eye-related:</b> <ul style="list-style-type: none"> <li>• eye pain</li> <li>• pain while receiving the injection</li> <li>• burning, stinging, itching, redness, irritation of the eye</li> <li>• blurred, cloudy or decreased sharpness of vision</li> <li>• increased production of tears or watery eyes</li> <li>• a sensation that something is in your eye</li> </ul>	<b>Speak to your doctor if you have any of these side effects and they worry you.</b>

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>• moving spots (floaters) or shadows in your vision</li> <li>• small or distorted pupil</li> </ul>	

#### Serious side effects

Serious side effects	What to do
<b>Eye related:</b> <ul style="list-style-type: none"> <li>• redness or blood in and around the eye</li> <li>• bleeding into the eye causing a red tint to your vision</li> <li>• increase in eye pressure – symptoms include severe headache, eye pain, nausea and vomiting, blurred vision, eye redness</li> <li>• small marks or scratches on the eye surface with pain or tenderness when you touch the eye, gritty feeling in the eye</li> <li>• inflammation of the gel-like substance at the back of the eye – symptoms include hazy vision or a marked increase in floaters (moving spots)</li> <li>• sudden onset of the following: eye pain, increased discomfort, worsening eye redness, a higher number of floaters in your vision, or increased sensitivity to light – these are signs of a possible eye infection or inflammation</li> <li>• decrease or change in your vision which can be sudden or gradual, including blurred or dim vision, difficulty with vision at night, fading – these are signs of cataract or other serious eye disorders</li> <li>• sudden, brief flashes of light which is more likely to occur when you move your eye, heavy feeling in the eye</li> </ul>	<b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

#### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

## 7. Product details

This medicine is only available with a doctor's prescription.

### What VABYSMO contains

<b>Active ingredient (main ingredient)</b>	faricimab
<b>Other ingredients (inactive ingredients)</b>	Histidine Acetic acid Methionine Polysorbate 20 Sodium chloride Sucrose Water for injections

**Do not take this medicine if you are allergic to any of these ingredients.**

### What VABYSMO looks like

VABYSMO is a solution for injection for intravitreal use. VABYSMO solution is a clear to slightly milky, colourless to pale brown liquid, supplied in a glass vial or pre-filled syringe.

#### Vial (AUST R 369935)

Each VABYSMO carton contains one glass vial and one sterile 5 µm blunt transfer filter needle (18-gauge x 1½ inch, 1.2 mm x 40 mm).

#### Pre-filled syringe (AUST R 449965)

Each carton contains one glass pre-filled syringe and one sterile injection filter needle (30-gauge x ½ inch, 0.30 mm x 12.7 mm, Extra Thin Wall).

### Who distributes VABYSMO

VABYSMO is distributed in Australia by:

Roche Products Pty Ltd

ABN 70 000 132 865

Level 8, 30-34 Hickson Road

Sydney NSW 2000

Medical enquiries: 1800 233 950

This leaflet was prepared in September 2024.